Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the efficacy of ginger in reduction chemotherapy-induced nausea and vomiting in newly diagnosed breast cancer patients receiving doxorubicin(adriamycin)-based chemotherapy.

Protocol summary

Summary

Given the wide prevalence of breast cancer in females and chemotherapy- induced nausea and vomiting, a randomized trial designed to evaluate efficacy of ginger on chemotherapy-induced nausea and vomiting. Inclusion criterias include Females with breast cancer, all ages, Prescription of doxorubicin-based chemotherapy and no Previous chemotherapy. Exclusion criterias include uncompleted questionnaires, the receiving of adriamycin for less than three cycles and severe gastrointestinal or coagulation side effects. Targeted populaton include 110 patients that receive chemotherapy in Namazee hospital. Patients randomly assign to intervention group or control group. Both groups receive chemotherapy and standard anti-emetic drugs. Then,intervention group and control group receive Ginger and placebo capsules ,respectively. patients consume the drugs for three days then complete designed questionnaire.This process is repeated for three cycles. Recruitment time is 6 months, and duration and severity of nausea and vomiting is compared in both groups finally.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050517581N1**
Registration date: **2015-02-13, 1393/11/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-13, 1393/11/24

Registrant information

Name

Pejman Porouhan

Name of organization / entity

Shiraz University of Medical Sciences (Namazi Hospital)

Country

Iran (Islamic Republic of)

Phone

+98 71 1612 5337

Email address

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-08-06, 1393/05/15

Expected recruitment end date

2015-02-04, 1393/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of ginger in reduction chemotherapy-induced nausea and vomiting in newly diagnosed breast cancer patients receiving doxorubicin(adriamycin)-based chemotherapy.

Public title

Evaluation of the efficacy of ginger in reduction chemotherapy-induced nausea and vomiting in newly diagnosed breast cancer patients receiving doxorubicin(adriamycin)-based chemotherapy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: New diagnosed breast cancer ;All ages ;Female ;No previous chemotherapy ;Prescription of doxorubicin-based chemotherapy ;No gastrointestinal obstruction ;No coagulopathy ;Receiving of standard anti-emetic treatment ;Completion of ethic form ;No concurrent hormontherapy or radiotherapy. Exclusion criteria: Bleeding ;Development of gastrointestinal obstruction ;Uncompleted questionnaires ;Less than 3 cycle doxorubicin-based chemotherapy

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences' Ethics Committee

Street address

Shiraz University of Medical Sciences, central building, Zand AVE

City

Shiraz

Postal code

Approval date

2014-08-03, 1393/05/12

Ethics committee reference number

CT-P-9354-5694

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50.9

ICD-10 code description

Breast, unspecified

Primary outcomes

1

Description

nausea severity and duration

Timepoint

3-days

Method of measurement

questionnaire

2

Description

vomiting frequency and duration

Timepoint

3-days

Method of measurement

questionnaire

Secondary outcomes

1

Description

Coagulation disorders

Timepoint

3-weeks

Method of measurement

questionnaire

2

Description

gastrointestinal disorders

Timepoint

3-weeks

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: all patients with new breast cancer that assigned to this group randomly, should have Complete Blood Count before any cycle of chemotherapy and all of them receive standard anti-emetic treatment concurrent their chemotherapy (doxorubicin-based) then they receive additional anti-emetic treatment in this manner: 1) capsule ginger 250mg 2) 2 capsule (500 mg) every 12 hours 3) for 3 days in every cycle of chemotherapy 4) for 3 cycles of chemotherapy

Category

Treatment - Drugs

2

Description
Control group: all patients with new breast cancer that assigned to this group randomly, should have Complete Blood Cell before any cycle of chemotherapy and all of them receive standard anti-emetic treatment concurrent their chemotherapy(doxorubicin-based) then they receive additional anti-emetic treatment in this manner: 1)placebo capsule that has similar shape and size with ginger 250mg capsule 2) 2 capsule every 12 hours 3) for 3 days in every cycle of chemotherapy 4) for 3 cycles of chemotherapy

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazee Teaching Hospital
Full name of responsible person
Dr.Pejman Porouhan
Street address
Zand AVE, Namazee SQ
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr.Ali Poost Foroush Fard
Street address
Vice president for research, Central building, Shiraz University of Medical Sciences, Zand AVE
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr.Pejman Porouhan
Position
Radiation Oncology Resident
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty